

Neonicotinoid Proposed Interim Decisions

This effort reflects collaboration between BEAD, EFED, HED and PRD, and chemical teams for all 4 neonics from each division. The interdivisional team met regularly to discuss assessment progress, methods and make sure that the assessments addressed PRD's needs.

The assessments conducted by EFED and BEAD were highly refined.

Outline

- Overview
- Risk Management Approach
- Bee Risks and Benefits
- Bee Risk Mitigation
- Other Ecological Risk Mitigation
- Human Health Mitigation
- Other Considerations
- Next Steps

Overview

Nitroguanidine-substituted neonicotinoids (includes: imidacloprid, clothianidin, thiamethoxam, and dinotefuran) are:

- A class of systemic insecticides registered for foliar (ground and air), soil, seed, and tree injection applications to a wide variety of agricultural crops
- Non-agricultural uses include turf, ornamentals, flea treatment for pets, wood preservative, poultry house, and other residential and commercial indoor/outdoor uses
- Most poundages applied as seed treatment for corn and soybean

Chemical	Est. annual usage (lbs/yr)	Major uses (lbs/year)
Clothianidin	1,500,000	Corn (seed treatment; 1,400,000)
Imidacloprid	1,120,000	Soybean (seed treatment, 430,000) Cotton, Potato, Wheat (all app. methods, 100,000 ea.)
Thiamethoxam	919,000	Corn (seed treatment; 300,000) Cotton (foliar, soil, seed; 160,000) Soybean (seed treatment; 300,000)
Dinotefuran	22,500	Cantaloupes (5,000) Rice (4,000)

Overview

USEPA Regulatory history

- Registration review began in 2008 with imidacloprid, then others in 2011
- Public concern over pollinator issues related to incidents (2008)
- Voluntary label restrictions implemented in "Bee Box" (2013)
- Hold placed on new uses to pollinator attractive crops (2015)
- Voluntary product cancellations as a result of an ESA lawsuit (March 2019)

States

- Seven states have passed legislation that address neonic issues
 - MD, VT and CT; restricted homeowner use
 - OR banned use on certain trees
 - NJ required beekeeper notification
 - CDPR requires risk management plan by 2020
- Many states have implemented state-wide pollinator protection plans (MP3s); AAPCO maintains inventory

International

- EU – banned on all outdoor use (2018)
- Canada – prohibited foliar and soil applications for certain uses (e.g., pome fruit, stone fruit, tree nuts, cucurbits) for pollinator risk (2019); proposed cancellation of all outdoor uses for aquatic risk (2018)

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Let's make sure our verbal intro to this slide hits hard on incidents and neonics in the media

Overall Risk Management Approach

Risk Management Priorities

- Human Health Risks of Concern (residential and occupational)
- Ecological Risks of Concern
 - Pollinators (bees) - from multiple uses
 - Birds and Mammals – from consuming treated seed
 - Aquatic Invertebrates – mainly from foliar application to multiple uses

Early Stakeholder Engagement

- Goals
 - To inform risk assessments and understanding of exposure to bees
 - To better understand benefits of uses preliminarily identified with risks of concern
- Stakeholders: Federal and state partners (USDA, OPMP; SFIREG, AAPCO, and NASDA; IR-4; Growers; Registrants; Other Stakeholders (American Hort, NALP, NPMA)

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In talking about risk management priorities, start out by letting the group know that these are the areas where the risk assessments indicated mitigation was needed, but that per our regs, we considered benefits extensively in our risk benefit calculus where appropriate, and this information is woven throughout our forthcoming discussion on mitigation

Bee Risk Management Approach

Declines in general honey bee populations are due to multiple factors, however through our risk assessment we have identified certain neonicotinoid uses where risk estimates indicate lethal effects to hives are expected.

Goal: To preserve the plant protection benefits of neonicotinoids, while implementing targeted risk reductions, particularly to honey bees which provide a benefit to agriculture through pollination services.

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Pollinator Protection Focus

- Focus on honey bees due to special economic benefits
 - 2017 USDA NASS Honey report estimates value of commercial pollination services at \$435 million (increasing)
 - 2017 USDA Honey Report estimates value of honey production at \$318 million (declining)
- Non-honey bees provide a significant contribution to pollination services
 - Some used for commercial pollination (bumble bees, leafcutter bees, blue orchard bees)
- Other pollinators expected to benefit from mitigation (i.e., rate reductions, spray drift reduction)

We propose Deliberative Process / Ex. 5

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Pollinator Risk Mitigation Summary Table

	High Benefit	Medium/Low Benefit
High Risk	Deliberative Process / Ex. 5	
Low Risk		

Ecological Risk - Bees

Lines of evidence considered in making risk call

- Based on crops that are attractive to bees
- Based on agronomic practices (e.g., harvest time relative to bloom)
- Comparison of expected residues to adverse effects level for hives (residues above NOAEC and LOAEC)
 - Considered duration and frequency of exceedance
 - Considered magnitude of exceedance
 - Ratio of max residue value to NOAEC/LOAEC
 - % of diet from the treated field needed to reach the NOAEC/LOAEC
 - Considered usage and geographic scale/spatial distribution of exposure
- Major Categories of Incidents
 - Bee kills from dust-off from corn seeds treated with clothianidin
 - Bee kills from ornamental tree applications
 - Bee kills from drift of spray application to agricultural fields

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Risks of concern result primarily from foliar applications and some soil applications
Risks are estimated to extend >1,000 ft from the edge of the field (foliar spray)

Benefits Assessments

- BEAD evaluated the impacts of multiple mitigation options depending on the risks being considered by use site (multiple assessments)

Methodology

- BEAD identifies key pests and alternatives based on recent usage data and extension literature
- Impact of mitigation (restriction) is measured by increased cost/acre, reduced revenue/acre via yield and/or quality loss with use of alternatives

Conclusions

- In general, neonics' advantages are:
 - Fairly broad spectrum: control sap-sucking insects, many of which vector disease; Individual a.i.s control somewhat different pests
 - Systemic and contact activity
 - Systemic: residual control for an extended period of time
 - Contact: immediate control (stops-feeding activity) reduces disease vectoring
 - Often comparatively inexpensive and effective
- In general, alternatives include:
 - organophosphates, pyrethroids, and carbamates; other neonic groups

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Risk Mitigation – Bees (agricultural use)

Highest Benefit Uses: Uses where neonicotinoids play a critical role in risk management to the extent that certain risk mitigation measures targeted at reducing pollinator exposure would have significant impacts on the use (i.e., no reasonable alternatives exist or existing alternatives pose potential increased risks to human health)

Mitigation Measures

- Rate Reduction (annual) – Cotton, Pome Fruit, Stone Fruit
 - Rate reductions selected to have minimal impact on most applications – goal is to limit flexibility for highest rates where applied rarely
 - Cotton is indeterminate blooming, increasing impacts of any pre-bloom interval
 - Also reduces risks to aquatic invertebrates
 - Risk reductions extend off-field
- Pre-bloom Application Interval – Pome Fruit, Stone Fruit, and Tree Nuts (thiamethoxam and dinotefuran only)
 - Majority of benefit occurs post-bloom, other neonicotinoids already prohibit pre-bloom application
 - Use crop stage to designate when applications may no longer occur (i.e., “Do not apply after swollen bud until petal fall”)
- No mitigation – Citrus, Grapes
 - Full use of neonicotinoids crucial to crops due to specific pest pressure (e.g., ACP, glassy-winged sharpshooter)

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Risk Mitigation – Bees (agricultural use)

Lower Benefit Uses: Uses where neonicotinoids are an important tool for certain pests or at certain time periods

Mitigation Measures

- Rate Reduction (annual) – Berries (non-grape)
 - Most berries are indeterminate blooming, increasing impacts of any pre-bloom interval
- Pre-bloom Application Interval – Fruiting Vegetables, Cucurbits, Tropical and Sub-Tropical Fruit
 - Use crop stage to designate when applications may no longer occur ("Do not apply after appearance of flower bud until petal fall")
 - For Tropical and Sub-Tropical Fruit, would only apply to highest usage crops (e.g., avocado, pomegranate)
- No mitigation – Root and Tuber, Herbs and Spices, Tropical and Sub-tropical fruits
 - Additional use characterization of acres grown and pollinator attractiveness limit extent of risks of concern

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Risk Mitigation – Bees (agricultural use)

Other Mitigation Measures

- For acute risk to bee (direct contact exposure during bloom)

Mitigation Measure

- Continuation of voluntary at-bloom application restrictions and pollinator advisory “bee box”
 - At-bloom restriction statement, applies to all food crops that are pollinator attractive
 - Prohibiting application during bloom expected to reduce both acute and chronic risk
- Bee hazard advisory language, also in “bee box”

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Poultry Litter

Mitigation Measure

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Risk Mitigation – Bees (Ornamental/Forestry and Turf uses)

Risk

- Strongest evidence of risk for ornamentals and forestry (moderate evidence for turf)
- Incidents of bee kills recorded for IMI, CLOTHI, and DINO
- Uncertainty considerations:
 - Very limited data set for a diverse set of plants
 - Unable to refine exceedances based on time

Residential Ornamental Mitigation:

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Production/Commercial Ornamental mitigation:

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Turf Mitigation:

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Risk Mitigation – Birds and Mammals

Seed Treatment

Risks

- For small-medium size birds and mammals, expected risk of concern with as little as 2-10% of diet
- Certain seeds are too big for small/medium sized passerine birds to ingest; some are pelleted
- Timing and duration of exposure to treated seeds at planting may limit the likelihood of exposure

Benefits

- Simple, effective control of soil pests and early-season above-ground pests
- Chlorpyrifos is likely other seed treatment; controls soil pests only
- Provide control with lower exposure through residues (pollinators) and aquatic runoff (invertebrates)

Proposed Risk Mitigation

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Talking Point: Stewardship efforts will also attempt to address issues from dust-off.

Risk Mitigation – Aquatic Invertebrates

Risks

- RQs range up to 2,130
- Neonicotinoids are especially mobile and persistent in aquatic environments
- Large amount of registrant and open literature data to support toxic effects
- Large amount of monitoring data (imid) to support exposure estimates

Benefits

- PRD and BEAD conducted a screen of uses with few acres treated and/or high PCT vs risk; did not consider mitigating uses with lower risk/high benefit
- Targeted remaining uses based on feasibility of rate reductions (BEAD assessment provided rate information)

Proposed Risk Mitigation

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Risk Mitigation – Aquatic Invertebrates

Proposed Risk Mitigation (continued)

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Spray Drift Mitigation

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Runoff Mitigation

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Good labelling practices and label clarification

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Human Health Risk Summary

	Dietary Exposure	Residential Exposure	Aggregate Exposure	Occupational Exposure
Imidacloprid	none	Turf – post-application	Turf – post-application	Handler risks for multiple scenarios – seed treatment
Clothianidin	none	none	none	Handler risks for seed treatment and aerosol (commercial bedbug) uses
Thiamethoxam	none	none	none	Handler risks for multiple scenarios – seed treatment
Dinotefuran	none	none	none	none

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Risk Mitigation – Human Health

Residential Risk – Imidacloprid Residential & Aggregate Risks of Concern

- Proposed Turf Mitigation: **Deliberative Process / Ex. 5**

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- Previous risks of concern identified for pet collar uses
 - Comments and data received during comments to preliminary assessment changed the Agency's risk conclusions; no longer a risk of concern

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Risk Mitigation – Human Health

Seed Treatment (Occupational Risk)

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Liquid Spray Application (Occupational Risk) – Additional PPE

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Other Regulatory Considerations

US EPA Stewardship Efforts

- Describes education and outreach programs for the care of spilled or uncovered treated seed
- Describes certain best management practices (BMPs) and technologies available to reduce dust off from application of treated seed
- Describes importance of efforts directed at improving bee health, including planting habitat, IPM for common bee pests, along BMPs and Manager Pollinator Protection Plans (MP3) to reduce exposure to bees from pesticides

Registrant Stewardship Proposal

- EPA reached out to the neonic technical registrants to develop a voluntary neonic stewardship program. The registrants proposed a plan to work together to improve and expand existing stewardship efforts
- Includes registrant out-reach to growers to identify applicable BMPs; and,
- Promotes consistency and collaboration, and utilizing their wide network of partners to amplify their existing stewardship efforts.

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Other Regulatory Considerations

Seed Dust-Off

- Incidents and some field measurements indicate potential for high risk to bees in certain scenarios (corn seed planting)

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Pending Registration Actions

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Petitions

- Currently 2 petitions related to neonicotinoids pending outcome of these decisions
 - Clothianidin risk to pollinators
 - Seed Treatment; exemption for treated seed

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Suggested talking point: reiterate that the majority of neonic usage is on seed treatments (for corn).

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Continued Stakeholder Engagement

Stakeholder Outreach

- PRD recently reached out to registrants and others (e.g., USDA, CDPR) to discuss initial scoping of mitigation
- Planned Outreach
 - Goals
 - Anticipate impacts of proposed mitigation
 - Improve how implementable and enforceable mitigation may be
 - Stakeholders
 - USDA, OPMP and IR-4
 - Growers
 - Registrants
 - States (SFIREG, AAPCO, NASDA)
 - Other Stakeholders (American Hort, NALP, NPMA)

Next Steps and Timeline

Anticipated Timelines for Completion

Activity	Year Date
Brief to OPP	August 21, 2019
Brief to OCSPP	September 16, 2019
Draft Documents ready for DD review & signature	October 18, 2019
Publication in FR and regulations.gov	Before the end of 2019

Planned Communications Materials for PID release:

- Desk statement
- OPP Update
- Website Update
- Q & A

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Questions?

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